

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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The Fourth Annual Educational Workshop—Current Topics in Regulatory Affairs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), in cosponsorship with the Orange County Regulatory Affairs (OCRA) discussion group, is announcing its Fourth Annual Educational Workshop intended to give the drugs, devices, and biologics industries an opportunity to interact with FDA's reviewers and compliance officers from FDA's centers and district offices. The main focus of this interactive workshop is to provide regulatory updates, guidances, and recommendations regarding new product submissions, postapproval changes, and postmarketing issues.

Date and Time: The meeting will be held on May 21 and 22, 2001, 7:30 a.m. to 5 p.m.

Location: The meeting will be held at The Irvine Marriott, 18000 Von Karman Ave., Irvine, CA.

Contact: Ramlah I. Oma, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949-798-7611, FAX: 949-798-7656, or Peri Ann DiRocco, OCRA discussion group, PMB 624, 5405 Alton Pkwy., suite 5A, Irvine, CA 92604, voice/FAX: 949-348-9141, e-mail: sdirocco@aol.com, www.ocra-dg.org.

Registration and Requests for Oral Presentations: Space is limited. Preregistration and confirmation are required. Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations directly to the OCRA Web site.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: March 20, 2001

March 20, 2001.

Ann M. Witt

Ann M. Witt,
Acting Associate Commissioner for Policy.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Mona Lisa Owen

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If you need special accommodations due to a disability, please contact Ramlah I. Oma at least 10 days in advance.

